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510(k) Summary for the PEAK PlasmaBlade™ TnA Tonsil and Adenoid Tissue Dissection Device

1. Submitter name and address:

PEAK Surgical, Inc.
2464 Embarcadero Way
Palo Alto, CA 94303
Phone: 650-331-3020
Fax: 650-331-3293

Contact: Lois Nakayama

Date Prepared: June 5, 2009

2. Device Name:

Trade Name:	PEAK PlasmaBlade™ TnA Tonsil and Adenoid Tissue Dissection Device
Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

3. Predicate Devices:

PEAK PlasmaBlade™ Tissue Dissection Device (K073057)
ArthroCare® ENT Plasma Wands™ (K070374)

4. Device description:

The PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device consists of a handpiece with integrated controls and cable, a shaft with a suction cannula, and two interchangeable tips. The tonsil tip consists of a curved and tapered insulated blade electrode with an opening in the center to allow for the evacuation of smoke and fluids. The adenoid tip consists of a flat, straight insulated blade electrode housed in a plastic tip with a bendable suction lumen that allows for the evacuation of tissue, fluids and smoke. Both tips connect to the suction cannula of the handpiece.

5. Intended Use:

The PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device is only intended to be used for the cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including adenoidectomy and tonsillectomy (Pharyngeal, Tubal, Palatine).

6. Technological Characteristics:

The PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device is similar to the predicate devices in that they are all electrosurgical instruments used to cut tissue and coagulate soft tissue, utilizing RF powered distal ends.

7. Performance Data:

Preclinical laboratory and performance tests were executed to ensure the device functioned as intended and met design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

8. Sterilization:

The PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device is provided sterile. The device is not intended for reuse or resterilization.

9. Conclusions:

By virtue of design, materials, function, and intended use, the PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device is substantially equivalent to FDA-cleared devices currently marketed in the United States. In establishing substantial equivalence to the predicate devices, PEAK Surgical evaluated the indications for use, materials incorporated, product specification and energy requirements of those systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

PEAK Surgical, Incorporated
% Ms. Lois Nakayama
Manager, Regulatory Affairs
2464 Embarcadero Way
Palo Alto, California 94303

Re: K083415
Trade/Device Name: PEAK PlasmaBlade™ TnA Tonsil And Adenoid Tissue Dissection Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: II
Product Code: GEI
Dated: June 1, 2009
Received: June 3, 2009

Dear Ms. Nakayama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083415

Device Name: PEAK PlasmaBlade™ TnA Tonsil and Adenoid Tissue Dissection Device

Indications for Use:

The PEAK PlasmaBlade™ TnA Tonsil and Adenoid Tissue Dissection Device is only indicated for cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including adenoidectomy and tonsillectomy (Pharyngeal, Tubal, Palatine)..

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083415